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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/663,889	09/18/2000	Gary J. Nabel	8642/91	6450

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EXAMINER

PARAS JR, PETER

ART UNIT	PAPER NUMBER
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1632

DATE MAILED: 05/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/663,889

Applicant(s)

NABEL ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 14 May 2003 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☐ The period for reply expires \_\_\_\_\_ months from the mailing date of the final rejection.
- b) ☒ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
  - (b) ☐ they raise the issue of new matter (see Note below);
  - (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
  - (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☐ Applicant's reply has overcome the following rejection(s): \_\_\_\_\_.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: None.

Claim(s) objected to: None.

Claim(s) rejected: 17-36.

Claim(s) withdrawn from consideration: 1 and 37-54.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 5. does NOT place the application in condition for allowance because: It is maintained that Applicant's claim to priority to parent applications 08/533,942, 09/031,572 and 09/426,325 is denied for the reasons of record. In particular, the priority claim is denied because the parent applications fail to fulfill the requirement of 35 U.S.C. 120 by not meeting the requirements of the first paragraph of 35 U.S.C. 112-written description and new matter. It is maintained that the instantly claimed embodiment of a "kit comprising a catheter and a nucleic acid comprising a gene encoding p21" has not been described in the instant specification. Applicant's arguments are centered on incorporation of the teachings of US patent 5,328,470, which allegedly discloses kits comprising an expression vector and a catheter. Applicants have argued that the holding in *Seversky* does not provide a basis for the Examiner's assertion that Applicant's incorporation-by-reference of the '470 patent does not satisfy the requirements of 35 U.S.C. 112, 1st paragraph because *Seversky* dealt with a continuation in part application which incorporated by reference a prior application. Applicants assert that *Seversky* states that a reference is properly incorporated "by means of an incorporating statement clearly identifying the subject matter which is incorporated and where it is to be found. Applicants also assert that the MPEP does not require that the relevant columns and line numbers of the '470 patent must be recited in the instant specification. In response, the Examiner asserts that *Seversky* in fact is relevant because it makes clear that the incorporating statement must clearly identify the subject matter which is incorporated and where it is to be found. The problem with the instant specification is that it in fact does not clearly identify the subject matter which is incorporated and where it is to be found in the '470 patent. It is maintained that the reference to the '470 patent in the instant specification (see page 10) generally discusses methods of administering a composition of the invention to a tumor and does not mention incorporation of a kit comprising a catheter and a nucleic acid comprising a gene encoding p21 or where support for such is found in the '470 patent such that it was to be incorporated into the instant specification. See page 10, lines 17-24. of the specification. To incorporate material by reference, the host document must identify with detailed particularity what specific material it incorporates and clearly indicate where that material is found in the various documents. See *In re Seversky*. *Seversky* does not discriminate saying that only in situations where a CIP is involved should the incorporated subject matter be specifically identified including where it is found in the referenced document. Moreover, the instant application has not claimed priority to the application that issued as the '470 patent. Applicants are reminded that material needed to accord an application a filing date may not be incorporated by reference. Therefore if a continuation or divisional application as originally filed incorporates by reference material omitted from the application papers, which is needed to accord the application a filing date, the application will not be entitled a filing date. See MPEP 201.06(c) and MPEP 608.01(p). See pages 2-4 of the Office action mailed on 3/11/03. It is further maintained that a new declaration is required because the instant application presents claims for subject matter not originally claimed or embraced in the statement of the invention (see above and on page 4 of the Office action mailed on 3/11/03). In view of the above discussion, the rejection under 112, 1st paragraph is maintained for the reasons of record and as discussed above. See pages 4-5 of the Office action mailed on 3/11/03. In view of the above discussion, the rejection under 35 U.S.C. 102 is maintained for the reasons of record and as discussed above. See pages 6-7 of the Office action mailed on 3/11/03.

**PETER PARAS**  
**PATENT EXAMINER**

